

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

As a precautionary measure, Lupin Pharmaceuticals, Inc. is initiating a recall of lots **S200756 Expiry: October 2024, S300218 Expiry: April 2025, and S300633 Expiry: September 2025** of **Voriconazole for Oral Suspension 40 mg/mL (75 mL when reconstituted)** to the **retail** level. These lots are being recalled due to a minor error identified in the reconstitution volume (water quantity) in the package insert. Product carton and product label state to reconstitute with 50mL while the package insert states to reconstitute with 46ml. 50mL is the correct reconstitution volume.

The erroneous reconstitution of Voriconazole for oral Suspension 40mg/mL (if reconstituted per pack insert instruction) would increase the potency of drug product which might lead to labelled adverse drug experience.

The recalled lots were distributed between November 2022 to January 2024 to wholesalers and distributors nationwide.

Voriconazole for Oral Suspension 40 mg/mL (75 mL when reconstituted) supplied as:

Strength	Lot(s)	Expiry	NDC	Description
40 mg/ mL (75 mL)	S300633	September 2025	43386-038-60	<u>Before reconstitution:</u>
	S300218	April 2025		Orange flavored, white to off -white granular powder.
	S200756	October 2024		<u>After reconstitution:</u>
				White to off-white suspension with orange flavor.